



# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: **BIGGADIKE, et. al.**

Serial No.: **10/066,964**

Group Art Unit: **1616**

Filed: **02/04/2002**

Examiner: **BADIO**

For: **FORMULATION CONTAINING ANTI-INFLAMMATORY ANDROSTANE DERIVATIVES**

Director of the United States Patent and Trademark Office  
Alexandria, VA 22313

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicants request that the references identified on Form PTO-1449 appended hereto be considered by the Examiner and officially made of record in accordance with the provisions of 37 CFR 1.97

- ☒ Copies of the references are enclosed on CD  
☐ Copies of the references were submitted in parent application Serial No. \_\_\_\_\_ (37 CFR 1.98(d))  
☐ A copy of the International Search Report which issued on International Application No. is submitted herewith. All of the publications cited in the International Search Report are listed on the attached form PTO-1449 and Applicants understand that copies have been supplied to the U.S. Patent Office by the International Bureau.

- A. ☐ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of the above application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 CFR 1.97(b).

OR

- ☐ The Information Disclosure Statement submitted herewith is being filed before the mailing of a first office action after the filing of a Request For Continued Examination under 37 C.F.R. 1.114 (37 C.F.R. 1.97(b)(4)).

- B. ☒ The Information Disclosure Statement transmitted herewith is being filed after three months of the filing date of the above application or the date of entry into the national stage as set forth in § 1.491 of an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last, but before the mailing date of either:  
 (1) a final action under § 1.113 or  
 (2) a notice of allowance under § 1.311,  
 whichever occurs first.

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

- ☒ Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under § 1.97(c) (\$240.00).

- C. ☐ The Information Disclosure Statement transmitted herewith is being filed after a final action under § 1.113, or a notice of allowance under § 1.311, whichever occurs first, but before the payment of the

issue fee. Also enclosed is a copy of the International Search Report which Issued on International Publication No.

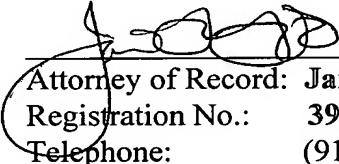
In accordance with the requirements of 37 CFR 1.97(d):

- ☐ Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ Applicant hereby petitions for the consideration of the accompanying Information Disclosure Statement. 37 CFR 1.97(d)(ii).
- ☐ The petition fee set forth in § 1.17(i)(1) (\$130.00) is submitted herewith.

☒ Please charge any required fees to Deposit Account No.07-1392.

☒ A duplicate copy of this paper is attached.

Respectfully Submitted,

  
\_\_\_\_\_  
Attorney of Record: James P. Riek

Registration No.: 39,009

Telephone: (919) 483-8022

Nov 16, 2007

CUSTOMER NO.: 23347

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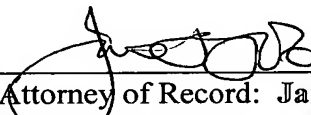
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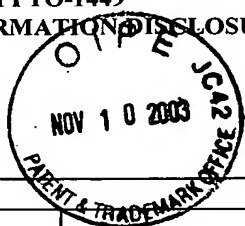
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**GROUP**  
 1616

**U.S. PATENT DOCUMENTS**

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	A1	3,067,197	12/04/62	Agnello et al.			
	A2	3,639,434	02/01/72	Oxley et al.			
	A3	3,828,080	08/06/74	May et al.			
	A4	3,856,828	12/24/74	Phillips et al.			
	A5	3,981,894	09/21/76	Phillips et al.			
	A6	3,989,686	11/02/76	Phillips et al.			
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	A9	4,188,385	02/12/80	Edwards			
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	A11	4,261,984	04/14/81	Alvarez			
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	A18	4,710,495	12/01/87	Bodor			
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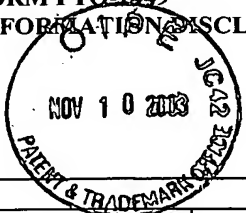
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	B1	92/14472	09/03/92	PCT			
	B2	95/31964	11/30/95	PCT			
	B3	96/19199	06/27/96	PCT			
	B4	97/05136	02/13/97	PCT			
	B5	97/15298	05/01/97	PCT			
	B6	97/24365	07/10/97	PCT			
	B7	97/46243	12/11/97	PCT			
	B8	98/43630	10/08/98	PCT			
	B9	99/01467	01/14/99	PCT			
	B10	99/25359	05/27/99	PCT			
	B11	99/32089	07/99	PCT			
	B12	00/38811	07/06/00	PCT			
	B13	00/57401	08/15/00	PCT			
	B14	01/04118	01/18/01	PCT			
	B15	01/15744	03/08/01	PCT			
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	B17	01/62722	08/30/01	PCT			
	B18	01/78736	10/25/01	PCT			
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	B21	01/78745	10/25/01	PCT			
	B22	02/00199	01/03/02	PCT			
	B23	02/00679	01/03/02	PCT			
	B24	02/007767	01/31/02	PCT			
	B25	02/008243	01/31/02	PCT			
	B26	02/013868	02/21/02	PCT			
	B27	02/26723	04/04/02	PCT			
	B28	02/053186	07/11/02	PCT			
	B29	02/066422	08/29/02	PCT			
	B30	02/070490	09/12/02	PCT			
	B31	02/076933	10/03/02	PCT			
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	B31 02/085296	10/31/02	PCT			
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	B33 02/100879	12/19/02	PCT			
	B34 03/013427	02/20/03	PCT			
	B35 03/033000	04/24/03	PCT			
	B36 03/035668	05/01/03	PCT			
	B37 03/040691	05/15/03	PCT			
	B38 03/042229	05/22/03	PCT			
	B39 03/042230	05/22/03	PCT			
	B40 0004773	10/17/79	EP			
	B41 0057401	08/11/82	EP			
	B42 0135476	03/27/85	EP			YES US4607028
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	B44 0416951	03/13/91	EP			
	B45 0418716	03/27/91	EP			YES WO9104252
	B46 0521455	01/07/93	EP			
	B47 0640616	03/01/95	EP			YES US5608093
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	B49 2336693	02/06/75	DE			NO
	B50 2538569	03/03/77	DE			NO
	B51 1384372	02/19/75	GB			
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	B53 1517278	07/12/78	GB			
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	B55 2140800	12/05/84	GB			
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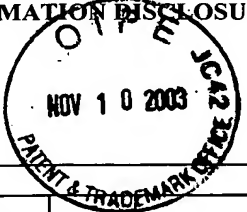
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	C1	Janette M. Mahoney et al., "Drug effects on the neovascularization response to silver nitrate cauterization of the rat cornea" Current Eye Research, Vol. 4, No. 5, 1985, pp. 531-535					
	C2	Richard A. Kenley et al., "An Automated, Column-Switching HPLC Method for Analyzing Active and Excipient Materials in Both Cream and Ointment Formulations," Drug Development and Industrial Pharmacy, Vol. 11 (9&10), 1985, pp. 1781-1796.					
	C3	R. Woodford et al., "Activity and bioavailability of a new steroid (Timobesone acetate) in cream and ointment compared with Lidex and Dermovate creams and ointments and Betnovate cream" Int'l Journal of Pharmaceutics, Vol. 26 (1985) pp. 145-155					
	C4	Denis J. Kertesz et al., "Thiol Esters from Steroid 17 $\beta$ -Carboxylic Acids: Carboxylate Activation and Internal Participation by 17 $\alpha$ -Acylates" J. Org. Chem., Vol. 51, 1986, pp. 2315-2328.					
	C5	Popper, T.L., et al., "Structure-Activity Relationship of a series of novel topical corticosteroids", Journal of Steroid Biochemistry 1987, 837 - 843					
	C6	John T. H. Ong et al., "Micellar Solubilization of Timobesone Acetate in Aqueous and Aqueous Propylene Glycol Solutions of Nonionic Surfactants", Pharmaceutical Research, Vol. 5, No. 11, 1988, pp. 704-708					
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	C10	Franklin I. Aigbirhio et al., "Automated Radiosynthesis of No-carrier-added [S-fluoromethyl- <sup>18</sup> F]Fluticasone Propionate as a Radiotracer for Lung Deposition Studies with PET" Journal of Labelled Compounds and Radiopharmaceuticals, Vol. 39, No. 7, 1997, pp. 569-584					
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	C13	N. Smith et al., "Comparison of the electroosmotic flow profiles and selectivity of stationary phases used in capillary electrochromatography," Journal of Chromatography A., Vol. 832, 1999, pp. 44-54					
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<b>OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)</b>							
	C15	Harold S. Nelson et al. "Fluticasone propionate/salmeterol combination provides more effective asthma control than low-dose inhaled corticosteroid plus montelukast," J. Allergy Clin. Immunol., Vol. 106, No. 6, December 2000, pp. 1088-1095					
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	C30	NAEDLE-RISHA R ET AL, "Dual components of optimal asthma therapy: scientific and clinical rationale for the use of long acting beta-agonists with inhaled corticosteroids", THE JOURNAL OF THE AMERICAN OSTEOPATHIC ASSOCIATION, Vol 101, No. 9, September 2001, pp.2001-09					
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	C33	PETER J. BARNES, "Efficacy of Inhaled Corticosteroids in Asthma", The Journal of Allergy and Clinical Immunology, Vol. 102, No. 4, pp. 531-538					
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	C36	US Publication No. 2002/0165211 publ. on 11/07/02					
	C37	US Publication No. 2002/0173496 publ. on 11/21/02					
	C38	US Publication No. 2002/0177581 publ. on 11/28/02					
	C39	US Publication No. 2003/0073676 publ. on 04/17/03					
	C40	US Publication No. 2003/0109511 publ. on 06/12/03					
	C41	US Publication No. 2003/0144257 publ. on 07/31/03					
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